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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,781	09/27/2000	Paul C. Daly	4538US	6751

7590 01/05/2005

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EXAMINER

WEINSTEIN, STEVEN L

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

LD

Office Action Summary	Application No. 09/670,781	Applicant(s) DALY, PAUL C.	
	Examiner Steven L. Weinstein	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 10, 12, 13, 15-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10, 12, 13, 15-17, and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 7, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazure ('207) in view of Blass et al (2/91), Stevens et al (Jan/Feb. 1999), Stevens et al (1997) and Frank (2000), further in view of Beckers ('746) and Hendriks et al ('242) further in view of Bublitz (4,211,338) for the reasons fully and clearly detailed in the Office actions mailed 3/13/02, 7/11/03 and 3/31/04.

Claims 12, 13, 15, 16, 22, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blass et al (2/91) in view of Stevens et al (Jan/Feb. 1999), Stevens et al (1997) and Frank (2000), further in view of Lazure et al, Beckers ('746) and Hendriks et al ('242), further in view of Bublitz (4,211,338) and Wisconsin State J.(2/6/91,p.4A) for the reasons fully and clearly detailed in the Office actions mailed 3/13/02, 7/11/03 and 3/31/04.

All of applicant's remarks filed 8/31/04 have been fully and carefully considered but are not found to be convincing. On page 8 of the amendment, it is urged that no one has practiced the invention. This urging is concerned with anticipation (under 35 USC 102). The rejection does not apply 35 USC 102 anticipation, but rather 35 USC 103, obviousness. Thus, in view of the art taken as a whole, the claims are novel (35 USC 102). However, to be patentable, claims must be novel (35 USC 102) and

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unobvious. As fully detailed previously in several Office actions, A prima facie case of obviousness has been established as evidenced by the art taken as a whole. Such evidence includes the fact that applicant is not the first provide food and medicines in single serve cup shaped containers; applicant is not the first to provide foods and medicines in aseptic packages and applicant was not the first to provide sterile sucrose solutions in the recited concentration as an analgesic to be administered orally to new borns. To therefore modify Lazure et al and substitute one conventional medicinal for another conventional medicinal in the single use container would have been obvious and to modify Blass et al and provide the conventional sucrose solution used as an analgesic in conventional individual packaging would also have been obvious in view of the art taken as a whole. It is urged that the art taken as a whole does not suggest combining the references. Since the art taken as a whole teaches packaging medicinals in single use containers and the medicinal is conventional, the motivation is clearly and fairly present to package the conventional medicinal in the conventional medicinal package.

The amendment also points to the Declaration of Ms. Bush for evidence of commercial success and the Declarations of Doctors Granger, Guttenberg and Yohannan for evidence of long felt need. The Declaration of Ms. Bush under 37 CFR 1.132 has been fully and carefully considered but is not seen to be sufficient to overcome the prima facie case of obviousness. The Declaration compares the sales of packages of sucrose solution to packages of a product that warms the sole of the infants foot. It is not clear how effective the latter is in providing pain relief to a

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newborn. The use of a sucrose solution as an analgesic for newborns is well established in the art. Therefore one would expect sales to be better for the well recognized sucrose analgesic solution. The Declaration also attributes the sales to the convenience of the aseptically packaged container filled with the sucrose solution. However, the convenience of single use containers containing food or medicinals is not an unexpected result. It is an expected result. Single use containers for all types of products, even non-edible, non medicinal products are provided for the convenience and the ability to discard the package once it has been opened and its contents used. The examiner notes that single use baby bottles containing aseptic formula have been employed in hospitals for new borns for many years because of their convenience.

The Declaration filed under 37 CFR 1.132 by Drs Yohanan, Guttenberg and Granger all urge the same thing. That is, they all urge a long felt need. The long felt need showing does not outweigh the strong case of prima facie obviousness. The aseptic, individual sucrose solutions provide convenience and safety. However, this is the same advantage that any aseptic medicinal or food provides the user.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven L Weinstein whose telephone number is (571) 272-1410. The examiner can normally be reached on Monday-Friday 7:00am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Weinstein/af
December 22, 2004

Steven Weinstein
STEVE WEINSTEIN
PRIMARY EXAMINER 1761
1/4/05